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10/081,641	02/22/2002	Patrick A. Haverkost	BSI-486US	2371

7590 05/24/2004  
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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/081,641

Applicant(s)

HAVERKOST ET AL.

Examiner

Sarah K Webb

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 9,12-16,18-29,34-46 and 48-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8,10,11,17,30-33 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-33,50,47, and 48, drawn to a stent delivery catheter, classified in class 623, subclass 1.11.
  - II. Claims 34-36 and 49, drawn to a method for deploying a stent in the body, classified in class 623, subclass 903.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case some of the method steps cannot be used with certain embodiments of the catheter.

3. This application contains claims directed to the following patentably distinct species of the claimed invention in Group I:

- |                     |              |
|---------------------|--------------|
| a. Figure 2         | e. Figure 5C |
| b. Figure 4A        | f. Figure 6  |
| c. Figure 4B        | g. Figure 7  |
| d. Figures 5A and B |              |

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1,2,10,11,17, and 30-32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with Rex Donnelly on 5/17/04 a provisional election was made without traverse to prosecute the invention of Group I, Species A, claims 1-8, 10, 11, 17, 30-33, and 47. Affirmation of this election must be made by

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applicant in replying to this Office action. Claims 9, 12-16, 18-29, 34-46 and 48-50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The structure claimed is indefinite because it is unclear which spatial relationship between the retrograde and anterograde sheaths is being claimed.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 1,2,10,11,30, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,201,757 (Heyn et al).

Heyn discloses a stent introducer (Figures 2 and 4) that includes a shaft (78) with a distal tip (84), inner sheath (100), stent (106), antegrade sheath (82) attached to the distal tip (84), and a retrograde sheath (94). Regarding claims 10 and 11, a "radial spacer" attached proximal to the distal tip provides space between the inner sheath (100) and the antegrade sheath (82). In Figure 4, arrows indicate the direction of movement of the antegrade and retrograde sheaths relative to the shaft. Anchoring means (102, 104) in both the antegrade portion and retrograde portion prevent axial travel of the stent relative to the shaft (78) when the sheaths are moved (column 6, lines 50-55).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3-6 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn in view of US Patent No. 6,042,589 (Marianne).

Heyn includes all the limitations of claims 3-6 and 47, but fails to form the anchoring means in the retrograde portion being a balloon. Heyn does include an anchoring means (104) in the retrograde portion for preventing axial movement of the

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stent. Marianne discloses a stent (7) introducer with a retracting sheath (16) and a proximal anchoring means in the form of a balloon (20). Marianne teaches that a balloon positioned in the retrograde portion of the stent provides better control of the stent during placement. The balloon not only prevents axial movement of the stent, it allows the stent to be repositioned during the procedure (column 3, line 35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the anchoring detent of Heyn with a balloon, as taught by Marianne, in order to provide the introducer with the capability for repositioning of the stent during the placement procedure.

Marianne further teaches that an inner sheath mounted over the shaft (8) can define an inflation lumen (22) for the balloon (20) (column 4, line 10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Marianne to adapt the inner sheath of Heyn to define an inflation lumen for the balloon of the device, as modified above.

9. Claims 7, 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn, as modified by Marianne.

The device of Heyn, as modified above, includes all the limitations of claims 7, 8, and 17 except for a medial sheath. In Figure 13 of Heyn, a medial sheath (246) is located between the inner and retrograde sheaths. It terminates proximally to the stent. Heyn teaches that such a "medial sheath" (246) can be provided as a proximal stop for the stent (column 11, line 27) so that it won't travel into the proximal region of the device. It would have been obvious to one of ordinary skill in the art at the time the

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invention was made to include a medial sheath in the modified Heyn device in order to prevent the stent from traveling proximally into the device.

10. Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn in view of US Patent No. 5, 445, 646 (Euteneuer).

Heyn includes all the limitations of claims 31 and 33, except for making the anterograde sheath cover more of the stent than the retrograde sheath and overlapping the two sheaths. Euteneuer discloses a stent introducer in Figure 2 that is similar to Heyn. The device includes both a retrograde (14) and an anterograde (16) sheath. The anterograde sheath covers a greater portion of the stent than the retrograde sheath in order to provide an overlapping region. Euteneuer explains that the overlap forms a seal (column 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to lengthen the anterograde sheath of Heyn so that it overlaps the retrograde sheath, as Euteneuer teaches that this structure forms a seal around the stent.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 6, 290, 710 to Cryer et al. discloses an endoluminal introducer device with an anterograde sheath and proximal balloon (see Figure 4) that reads on many of the elected claims. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 605-1176. The examiner can normally be reached on Mon-Fri 8-4:30.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW  
05/19/04



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